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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
BROWN, STACY S

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,086	Applicant(s) POLO ET AL.	
	Examiner Stacy S Brown	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31* is/are rejected.

7)☒ Claim(s) *25 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election of Group VI, claims 25-28 is acknowledged. New claims 29-31 are added. Claims 1-31 are pending. Claims 25-31 are examined. Claims 1-24 are withdrawn from consideration being drawn to non-elected inventions.

Election/Restrictions

2. Applicants mainly argue that there is no burden of search for the examination of all Groups. Applicants argue that because the groups are classified in the same class and have a common feature of alphavirus particles, that one search would encompass all claims. However, the groups of claims are directed to different methods of using, purifying, quantitating or producing alphavirus particles. The asserted novelty of the invention is not alphavirus particles, but the methods of making, using, producing, purifying and quantitating. These methods have different method steps, reagents, outcomes, function and effects. Therefore, the restriction requirement is deemed proper and made FINAL.

Claim Objections

3. Claims 25 and 31 are objected to because of the following informalities:

- Claim 25, section c) refers to a vector "particle", which should be "particles".
- Claim 31, consistent terminology should be used for "quantified alphavirus replicon particles". The other claims use "quantified alphavirus replicon vector particles".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 25, "alphavirus replicon vector particles" is not clear. Throughout the specification there are references and definition for replicons, vectors and vector replicons in paragraphs [0040] and [0041]. For purposes of compact prosecution, "alphavirus replicon vector particles" will be interpreted as replicon particles (according to [0041]). There does not appear to be a clear definition of "alphavirus replicon vector particles". Clarification is requested.
- In claim 25, there should be a step indicating that enumeration of the resulting plaques indicates the quantity of replicon vector particles. According to paragraph [0008], the presence or absence of contaminating replication-competent is determined. Is the method quantitating replication-defective or replication-competent particles? Clarification of the method is requested.
- In claim 30, it is unclear at what step in the process the agar is applied.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dubensky, Jr. *et al.* (5,789,245).

The claims are drawn to a method for quantitating alphavirus replicon vector particles comprising:

a) Providing a population of packaging cells

b) Contacting packaging cells with alphavirus replicon vector particles and allowing time for cells to be infected with particles

c) Incubating cells and allowing time for production of particles; and

d) Enumerating the number of resulting plaques.

Claim limitations are drawn to: the expression of structural proteins required for packaging particles; expression cassettes expressing alphavirus capsid protein and glycoprotein (E1 and E2); and overlaying the infected cells with agarose. Also claimed is a composition comprising the quantified particles.

Dubensky teaches methods of making alphavirus structural protein expression cassettes that express C, 6K, E3, E2 and E1 (col. 5, lines 27-36). Also disclosed are alphavirus producer cell lines, packaging cells, and recombinant alphavirus particles (cols. 10-11).

- According to Dubensky, a recombinant alphavirus particle is a capsid that contains an alphavirus vector construct. The vector construct lacks structural protein expression, which is supplied by the expression cassettes (cols. 10-11).
- According to the instant specification, an alphavirus replicon vector particle is a virion unit containing an alphavirus RNA vector replicon. The particle supplies the structural proteins that the replicon lacks (paragraphs [0041-0041]).

Dubensky also discloses that plaque assay can measure alphavirus vector construct titer (cols. 19-20, bridging paragraph).

Since Dubensky says that plaque assaying can measure titer, and Dubensky's product appears to be the same as Applicant's product, the method is anticipated.

Dubensky does not specifically mention the steps of infection and incubation, or of overlaying infected cells with agarose. However, it would have been obvious to practice Dubensky's plaque assay with the cited steps. One would have been motivated to do the specific steps because those steps define plaque assays. It would have been obvious to apply the agar layer over the cells because plaque assays are routinely performed with an agar overlay. One of ordinary skill would know that methods of plaque assays are well-known and routinely practiced. Overlaying infected cells with agarose would have led one to reasonably expect a successful plaque assay.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Office notes that the asserted novelty is that quantitating vector particles is unknown. However, since quantitating particles of many types is known and practiced, Applicant must show how their assay is different and an improvement over the prior art's assay.

Conclusion

6. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are

unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown
April 19, 2002

HANKYEL T. PARK, PH.D
PRIMARY EXAMINER